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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,780	03/07/2002	Mohamend El-Sherbeini	20519P	9669

210 7590 01/28/2005

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EXAMINER
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PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/070,780

**Applicant(s)**

EL-SHERBEINI ET AL.

**Examiner**

Ginny Portner

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-11,15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 4-8 is/are allowed.
- 6) ☒ Claim(s) 9 and 17 is/are rejected.
- 7) ☒ Claim(s) 10 and 11 is/are objected to.
- 8) ☐ Claim(s) \_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 2-3,12-14 and 16 have been canceled.

Claims 1,4-11,15,17 are pending and under consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Objections/Rejections Maintained***

2. The disclosure objected to for informalities: The Specification still has blank lines on pages 20-21, for reasons of record .

3. Claim 9 rejected under 35 USC 112, second paragraph for being “silent with respect to the expression of the encoded polypeptide”, which constitutes an incomplete method as it omits essential steps and not defining an essential structural cooperative relationships of elements, specifically structural components of the host cell and growth/culture conditions that result in expression of the encoded MurC polypeptide of SEQ ID NO 2 which was addressed through asking “Does the expression vector express the MurC polypeptide?” for reasons of record page 10, of Office Action 06172004, and responses set forth below.

#### ***Response to Arguments***

4. The disclosure objected to for informalities is traversed on the grounds that the blank lines would be addressed upon receipt of a notice of allowance.

5. It is the position of the examiner that the Specification still has blank lines on pages 20-21 and is therefore still objected to for minor informalities.

6. The rejection of claim 9 under 35 USC 112, second paragraph is traversed by stating “Claims 4-5, 7-11 and 17 are rejected under section 112, second paragraph, for a

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variety of grammatical and formal matters (Action, paragraph 43). The claims have been amended. In view of the amendments, Applicant requests the withdrawal of the rejections.”

7. It is the position of the examiner, that while many of the issues raised in the last Office Action under 35 USC 112, second paragraph were resolved through amendment of the claims, claim 9 was not amended in such a way as to resolve all of the issues raised under 35 USC 112, second paragraph.

8. The examiner stated that claim 9 was “silent with respect to the expression of the encoded polypeptide”. As the method is a method of determining the activity of a candidate compound on the expressed MurC polypeptide, expression of the polypeptide would be critical to the claimed method. As no expression step is set forth in the claim, and the claim is silent with respect to expression of the polynucleotide that encodes the MurC polypeptide, the claimed method is an incomplete method as it omits essential steps. Additionally there is a lack of clarity between the structural elements recited in the claim to show a cooperative relationship between the expression vector regulatory elements, the polynucleotide that encodes the polypeptide, and the candidate compound which must interact with the MurC polypeptide in order to determine anything. No specific structural components of the expression vector, host cell and growth/culture conditions that result in expression of the encoded MurC polypeptide of SEQ ID NO 2 were set forth in the amended claim; this is a critical issue was raised by the examiner by asking the question “Does the expression vector express the MurC polypeptide?” (see page 10, of Office Action 06172004).

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The instant Specification defines the expression vectors to include the inducible regulatory elements in invention. (see sections defining the invention cited below)

(Instant Specification, page 3, paragraph 3) An aspect of this invention is an expression vector including a polynucleotide encoding a *Pseudomonas aeruginosa* Murc protein, has a sequence corresponding to SEQ m NO:2. "In particular embodiments, the vector can have any of a **variety of regulatory regions** known and used in the art as appropriate for the types of host cells the vector can be used in." "In some preferred embodiments the regulatory regions provide for **inducible** expression". (Instant Specification, page 4, paragraph 1) "An aspect of this invention is a process for expressing a Murc protein of *P. aeruginosa* in a host cell." "In particular embodiments the expression is **inducible**".

In light of the definitions provided by the instant Specification that the expression vectors include inducible expression regulatory elements thus automatic expression of the encoded MurC polypeptide would not take place. The expression vector encoded polypeptide would not be contacted with the candidate compound based upon the defined invention utilizing inducible regulatory elements, therefore the claimed method would not afford the determination of any type of MurC activity based upon the encoded polypeptide unless culture conditions for induction and expression were carried out by the claimed method. The rejection is maintained for reasons of record, and responses set forth above.

*Amended Claims/New Grounds of Rejection*

*Claim Rejections - 35 USC § 112*

9. Claim 17 recites the limitation "relative activity" in line 1, and depends from claim 15, which no longer recites this phrase. There is insufficient antecedent basis for this limitation in the claim.

*Allowable Subject Matter*

10. Claim 9 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in the prior office action and maintained in this Office action.

11. Claims 10-11 are objected to as being dependent upon a rejected base claim, but would be allowable upon resolution of the issues raised with respect to claim 9 under 35 USC 112, second paragraph.

12. Claim 17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

*Conclusion*

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the


advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp  
January 24, 2005

  
**LYNETTE R. F. SMITH**  
**SUPERVISORY PATENT EXAMINER**  
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